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AUTHORITY: 42 U.S.C. 11101–11152; 42 U.S.C. 1396r–2; 42 U.S.C. 1320a–7e

SOURCE: 78 FR 20484, April 5, 2013, unless otherwise noted.

Subpart A—General Provisions

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986 (HCQIA), as amended, title IV of Public Law 99–660 (42 U.S.C. 11101 *et seq.*) (hereinafter referred to as “title IV”), authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank (NPDB) to collect and release certain information relating to the professional competence and conduct of physicians, dentists, and other health care practitioners. Section 1921 of the Social Security Act (hereinafter referred to as “section 1921”), as amended, (42 U.S.C. 1396r–2) expanded the requirements under the NPDB and requires each state to adopt a system of reporting to the Secretary adverse licensure or certification actions taken against health care practitioners, health care entities, providers, and suppliers, as well as certain final adverse actions taken by state law and fraud enforcement agencies against health care practitioners, providers, and suppliers. Section 1128E of the Social Security Act (hereinafter referred to as “section 1128E”), as amended, (42 U.S.C. 1320a–7e) authorizes the Secretary to implement a national healthcare fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken by Federal Government agencies and health plans against health care practitioners, providers, and suppliers. Information from section 1921 and section 1128E is to be reported and distributed through the NPDB. The regulations in this part set forth the reporting and disclosure requirements for the NPDB, as well as procedures to dispute the accuracy of information contained in the NPDB.

[78 FR 20484, April 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.2 Applicability.

The regulations in this part establish reporting requirements applicable to hospitals, health care entities, Boards of Medical Examiners, and professional societies of health care practitioners which take adverse licensure or professional review actions; state licensing

or certification authorities, peer review organizations, and private accreditation entities that take licensure or certification actions or negative actions or findings against health care practitioners, health care entities, providers, or suppliers; entities (including insurance companies) making payments as a result of medical malpractice actions or claims; and Federal government agencies, state law and fraud enforcement agencies and health plans that take final adverse actions against health care practitioners, providers, and suppliers. They also establish procedures to enable individuals or entities to obtain information from the NPDB or to dispute the accuracy of NPDB information.

[78 FR 20484, April 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.3 Definitions.

Adversely affecting means reducing, restricting, suspending, revoking, or denying clinical privileges or membership in a health care entity.

Affiliated or associated refers to health care entities with which a subject of a final adverse action has a business or professional relationship. This includes, but is not limited to, organizations, associations, corporations, or partnerships. This also includes a professional corporation or other business entity composed of a single individual.

Board of Medical Examiners, or Board, means a body or subdivision of such body which is designated by a state for the purpose of licensing, monitoring, and disciplining physicians or dentists. This term includes a Board of Osteopathic Examiners or its subdivision, a Board of Dentistry or its subdivision, or an equivalent body as determined by the state. Where the Secretary, pursuant to section 423(c)(2) of the HCQIA (42 U.S.C. 11112(c)), has designated an alternate entity to carry out the reporting activities of § 60.12 of this part due to a Board's failure to comply with § 60.8 of this part, the term Board of Medical Examiners or Board refers to this alternate entity.

Civil judgment means a court-ordered action rendered in a Federal or state court proceeding, other than a criminal proceeding. This reporting requirement does not include Consent Judgments

that have been agreed upon and entered to provide security for civil settlements in which there was no finding or admission of liability.

Clinical privileges means the authorization by a health care entity to a health care practitioner for the provision of health care services, including privileges and membership on the medical staff.

Criminal conviction means a conviction as described in section 1128(i) of the Social Security Act.

Dentist means a doctor of dental surgery, doctor of dental medicine, or the equivalent who is legally authorized to practice dentistry by a state (or who, without authority, holds himself or herself out to be so authorized).

Exclusion means a temporary or permanent debarment of an individual or entity from participation in any Federal or state health-related program, in accordance with which items or services furnished by such person or entity will not be reimbursed under any Federal or state health-related program.

Federal Government agency includes, but is not limited to:

- (1) The U.S. Department of Justice;
- (2) The U.S. Department of Health and Human Services;
- (3) Federal law enforcement agencies, including law enforcement investigators;
- (4) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the U.S. Department of Defense and the U.S. Department of Veterans Affairs; and
- (5) Federal agencies responsible for the licensing and certification of health care practitioners, providers, and suppliers.

Formal peer review process means the conduct of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing.

Formal proceeding means a proceeding held before a state licensing or certification authority, peer review organization, or private accreditation entity that maintains defined rules, policies, or procedures for such a proceeding.

Health care entity means, for purposes of this part: